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In re: Patent Term Extension  
Application for  
U.S. Patent No. 4,840,896

JAN 30 2007

## NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,840,896, which claims the human biological product OVIDREL® (choriogonadotropin alfa (recombinant human chorionic gonadotropin (r-HCG))) is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1044 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 1044 days.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of March 15, 2006 (71 Fed. Reg. 13406). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1485) + 302 \\ &= 1044 \text{ days (2.9 years)}\end{aligned}$$

Since the regulatory review period began November 1, 1995, after the patent issued (June 20, 1989), the entire regulatory review period has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	4,840,896
Granted:	June 20, 1989
Original Expiration Date <sup>1</sup> :	June 20, 2006
Applicant:	Vermuri B. Reddy, et al.
Owner of Record:	Genzyme Corporation

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<sup>1</sup>Subject to the provisions of 35 U.S.C. § 41(b).

Title: Heteropolymeric Protein

Product Trade Name: OVIDREL® (choriogonadotropin alfa (recombinant human chorionic gonadotropin (r-HCG)))

Term Extended: 1044 days

Expiration Date of Extension: April 29, 2009

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450.

By FAX: (571) 273-7754

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7754.



Kathleen Kahler Fonda  
Legal Advisor  
Office of Patent Legal Administration  
Office of the Deputy Assistant Commissioner  
for Patent Policy and Projects

cc: Office of Regulatory Policy  
HFD - 7  
5600 Fishers Lane (Rockwall II Rm. 1101)  
Rockville, MD 20857

Attention: Beverly Friedman

Re: OVIDREL®  
FDA Docket No.: 2005E-0256